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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ZEMAN, H

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 09/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/527,440

Applicant(s)

NAKAE ET AL.

Examiner

Mary K Zeman

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11 and 19-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11 and 19-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                             | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8, 10</u> . | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1631, Examiner Mary K Zeman. Claims 1-8, 11 and 19-29 are pending in this application. Claims 20-29 are newly added.

Applicant's arguments filed 6/19/01 have been fully considered but they are not persuasive. Any non-reiterated rejections have been withdrawn.

### ***Information Disclosure Statement***

The IDS statements filed 1/9/01 and 4/6/01 have been considered. An initialed copy of the PTO-1449 forms are included with this action.

### ***Specification***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See page 32 of the specification.

The disclosure is objected to because of the following informalities: The brief description of Figure 6 does not set forth the SEQ ID NO:s for each individual sequence, nor are those identifiers present within Figure 6. Applicant should amend the brief description of Figure 6 to clearly associate each polynucleotide with its particular sequence identifier. (changes to the drawing are not necessarily required.)

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 11 and 19-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention. *This is a new grounds of rejection necessitated by Applicant's amendment.*

The amendment to claims 1, 7, 8, 11, 19 and the limitation in claims 20-29 reciting "a plurality of DNA nucleotide sequences of human genomes" is unclear. A genome is the entire set of chromosomal DNA in a cell. The human genome is generally identified as a single genome. Applicant may intend the phrase "a plurality of DNA sequences from the human genome." Alternatively, many different genes exist within a genome, and those genes can vary from person to person. If this is what Applicant intends, the phrase "a plurality of DNA sequences of human genes..."

The deletion of the term "different" in the first means clause of 1, 7, 8, 19 and 20-29 results in a lack of antecedent basis for the phrase "the plurality of different DNA..." in the second and third means clauses.

The amendment to claims 1, 7, 8, 11, 19 and the limitation in claims 20-29 reciting "wherein said extraction conditions including a predetermined length" is grammatically incorrect. "wherein said extraction conditions include a predetermined length" would be correct.

The amendment to claims 1, 7, 8, 11, and 19 reciting "each of said plurality of different partial sequences being extracted from different exons" is entirely unclear. Do the exons come from different genes, or the same gene? One gene can have a multitude of exons which are spliced together during transcription to create a cDNA, which is then translated to a protein. It is entirely unclear what one would do with exons from differing genes within each set of primers. Further, is the information about where the exons begin and end identified in the database for every sequence of the genome? If so, that is not clear, and such information is not described in the specification. If not, how could one then extract the correct sequences? If the database only contains known and analyzed sequences wherein the introns and exons have been identified etc, the claims should recite such limitations.

It is unclear what characteristics the primers must have as a result of the "determining" step in claims 1, 7, 8, 11, 19, and 20-29. Differing types of primers would have to have differing characteristics. Primers for normal PCR have to include a forward and a reverse primer to one sequence. Primers for RT-PCR generally have an oligo dT sequence at the end of one primer.

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However, single strand amplification uses single primers, but could be envisioned as for the amplification of different regions of the same sequence.

It is completely unclear how the plurality of pairs of undefined primers are correlated to a genetic function in the last clause of claims 1, 7, 8, 11 and 19-20, 22, 24, 26, and 28. If the database contains new, or unknown sequences- *there is no genetic function to correlate*. Applicant did not address this issue in the response. Further, this step as amended does not require that the pair of primers be correlated or matched up with the sequence set forth in the second means clause of the claim.

The changes made to claim 1 render the meaning of claim 2 unclear. How can the control means select primers before the "partial sequences" are identified, and before the "determining step"? How does this limit the system of claim 1? Similarly, claim 3 (dependent from claim 2) is completely unclear as to where it fits in the system. Claim 1 recites a means for a selection condition in the beginning of the claim, and claim 2 recites a different means for a selection condition. It is entirely unclear what is meant by these limitations.

Claim 4 still recites the phrase "mutually different" which was rejected previously. Further, there is no antecedent basis for "said certain base length." If claim 4 is intended to modify the first clause of the system of claim 1, no base length is recited in that clause. The phrase "a predetermined base length" is not set forth until the third clause of the system.

It is unclear where the limitations of claim 5 should be inserted into the system of claim 1.

Claim 6 does not clearly define how the second database is to be used in the system of claim 1, due to the presence of too many "or" clauses, and reference to multiple clauses in the system of claim 1.

Further in claim 20, the metes and bounds of the phrase "means for positioning exons associated with genetic functions of interest on the plurality of different DNA nucleotide sequences" are entirely unclear. An exon is a region of a polynucleotide or genomic sequence that encodes a part of a protein. The exon itself has no "genetic function" nor is it physically "positioned" "on a nucleotide sequence." The characteristics of an exon can be tentatively identified in a genomic sequence, and that information can be associated with a region of the sequence in a database- but this is not what the claim sets forth.

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In the fifth clause of claim 20, are more than one partial sequence associated with one genomic sequence? Or does each gene only have one partial sequence from which to derive two primers?

Claims 21, 23, 25, and 27 each recite improper Markush language referring to options (a)-(e), and the limitations do not make sense when compared to the system of claim 20. It is entirely unclear where this limitation should be placed in the system of claim 20. For example, is the exon predicting program part of the means of positioning? The means of collating? What is the intent of (c) and (d) "from at least one EST Database?" This does not make grammatical sense in claim 21, or in claim 20, nor does it clearly identify where it should be added to the system of claim 20. Further, the specification does not identify what "a SNP potential" is. Either a polynucleotide has a single nucleotide polymorphism, (SNP) or it does not. In theory, ANY single nucleotide of a polynucleotide in a database of polynucleotides has some *potential* for being polymorphic. Further, option (e) also makes no grammatical sense in context, and the limitation "having no known function" completely is at odds with the notion of "genetic functions of interest." How can the system operate if it is supposed to position genetic functions of interest, or correlate genetic functions of interest when you don't know what the function is?!

The above comments about claim 21 equally apply to claims 23, 25 and 27.

Claim 26 is confusing as it begins with a computer-implemented method, then switches to a method of analyzing a sample of DNA- this step refers to PCR fragments, but no steps of performing PCR are in claim 26. The end of this clause appears to say that the analysis is performed with a storage media, but this does not make sense. Also, no types of primers are distinguished by the method of claim 26, so where does the type of primer become an indicator? How does this indicator afford the PCR fragments anything? The final clause of claim 26 defining the storage media is not clearly related to the method being claimed, or the steps that have been performed in that method.

Applicant is encouraged to carefully read the claims as they are now pending before attempting any further amendments. Any further amendments to the pending claims must clearly set forth the system and method described in the specification, and at least be grammatically

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correct, with dependent claims clearly identifying what and where in the preceding claim the limitation should be read.

### *Conclusion*

As the nature of the invention is not clearly set forth in the claims, the examiner is unable to apply art. Upon the submission of acceptable claims, the art rejections of record, as well as the art cited on the information disclosure statements will be reassessed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

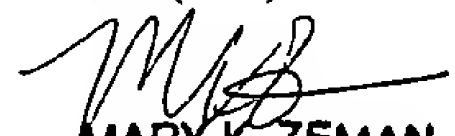
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can generally be reached between the hours of 7:30 am and 5:00 pm Monday through Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028.

The official fax number for this Art Unit is (703) 308-4242. An unofficial fax number, direct to the Examiner is 703 746 5279. Please call prior to use of this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst Tina Plunkett whose telephone number is (703) 305-3524.

mkz  
8/15/01

  
MARY K. ZEMAN  
PATENT EXAMINER  
AU 1631